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| 10/813,447 | 03/29/2004 | Matthew Baker | STJUDE 3.0-011 | 4689 |
| 530 7590 08/02/2010 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090 | | | EXAMINER RYCKMAN, MELISSA K | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/813,447

Applicant(s)

BAKER ET AL.

Examiner

MELISSA RYCKMAN

Art Unit

3773

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/15/10.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, 10-20 and 35-62 is/are pending in the application.
- 4a) Of the above claim(s) 51-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10-14, 17-20, 35-50 and 62 is/are rejected.
- 7) ☒ Claim(s) 15 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to claims filed 6/15/10. Applicant's arguments, filed 6/15/10, with respect to Logan having the proximal portion remaining the same when the distal end is in the expanded and constrained conditions have been fully considered and are persuasive. The finality of the office action dated 3/15/10 has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,8,10-14,17,18,35-47,and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Gifford, III (U.S. Patent No. 5,904,697).

Regarding claims 1, 35 and 62 Gifford teaches a connector assembly (208, Fig. 17A) for use in making an anastomotic connection between an opening prepared at an end of a graft tissue (150) conduit and an aperture in a side wall of a body tissue conduit in a patient (Fig. 17D) comprising: a body (208) disposed annularly about a longitudinal axis and having axially spaced distal and proximal portions, the distal portion (216) having annular element (arranged annularly) comprising a graft retention component (216 aids in retaining the graft by securing 218 to graft 150 in Fig. 17D) to secure the tissue of the graft tissue conduit about the opening to the connector

assembly, and the proximal portion having a plurality of annularly spaced body fingers (215) that extend radially out to engage the interior surface of the side wall of the body tissue conduit about the aperture (capable of engaging interior surface of the side wall of the body tissue conduit). The body has a constrained (Fig. 17A) and expanded (Fig. 17D) position, the distal end remains the same in both positions (216 same in Fig. 17A and 17D), while the proximal end changes from the plurality of body fingers (215) being parallel to the longitudinal axis (Fig. 17A) to extending radially outward (215 is extending outward from the opening 152 in the radial direction).

Gifford teaches a delivery tool (118) that aids in transforming the device from the constrained position (col. 25, ll. 60-65) to the expanded position (col. 25, ll. 60-65).

Regarding Claims 2 and 39, Gifford teaches the connector assembly defined in claims 1 and 35, wherein the graft retention component (216) comprises an annular inside-retention element (capable of attaching to the inside of the graft) configured to engage the interior surface of the graft tissue conduit about the opening (Fig. 17D).

Regarding Claims 3 and 40, Gifford teaches the connector assembly defined in claims 2 and 37, wherein the anastomotic connection (208) has an ostium diameter larger than a cross-section area of the graft tissue conduit in a direction orthogonal to the longitudinal axis (Fig. 17D).

Regarding Claim 4, Gifford teaches the connector assembly defined in claim 2, wherein the annular inside-retention element (216) is unitary with the distal portion of the body (Fig. 17A).

Regarding Claim 5, Gifford teaches the connector assembly defined in claim 2, wherein the annular inside-retention element (216) is coupled to the distal portion of the body (Fig. 17A).

Regarding Claim 6, Gifford teaches the connector assembly defined in claim 2, wherein the annular inside-retention element (216) includes a plurality of annularly spaced inside-retention members that have free ends configured to engage the interior surface of the graft tissue conduit about the opening (Fig. 17A).

Regarding Claim 17, Gifford teaches the connector assembly defined in claim 1, wherein the radially outward expansion of the plurality of annularly spaced body fingers (215) is an elastic bending (Fig. 17D).

Regarding Claim 18, Gifford teaches the connector assembly defined in claim 1, wherein the body has a medial portion between the proximal portion and the distal portion, wherein the medial portion includes at least one torsional element (central portion near 213 in Fig. 17A).

Regarding Claim 36, Gifford teaches the apparatus defined in claim 35, wherein the loading tool is external to the cannulation of the connector assembly (portion of the loading tool is external, Fig. 5E, col. 25, ll. 60-65).

Regarding Claim 37, Gifford teaches the apparatus defined in claim 35 further comprising a loading tool (119) having a body portion, wherein the body portion is configured to support the distal portion of the connector assembly and to define the resulting shape of the anastomotic connection external to the body tissue conduit (Fig. 5E).

Regarding Claim 38, Gifford teaches the apparatus defined in claim 37, wherein the loading tool further comprises at least one tissue holder (distal end 119, Fig. 5E) configured to engage the exterior surface of the graft tissue conduit about the opening and to hold the graft tissue conduit about the graft retention component of the connector assembly (fig. 5E).

Regarding Claims 41 and 47, Gifford teaches said annular element has a fixed cross-sectional area (Fig. 17A).

Regarding Claim 42, Gifford teaches said connector is circular (Fig. 17A).

Regarding Claim 43, Gifford teaches said graft retention component is a fixed part of the annular element (Fig. 3).

Regarding Claims 12-14,44,46, Gifford teaches an outside-retention element (218) configured to annularly engage the exterior surface of the graft tissue conduit (Fig. 17D) about the opening in the assembled condition. The outside-retention element is configured to be at least partially in the same plane and partially proximal to the inside-retention element (216, Fig. 17D)

Regarding Claim 45, Gifford teaches the outside-retention element (218) is hingedly coupled to the distal portion of the body (216 acts as hinge during placement of 218, Fig. 17D).

Regarding Claim 8, Gifford teaches the out-side retention element includes a plurality of annularly spaced out-side retention members (218, Fig. 17B)

Regarding Claim 10, Gifford teaches the outside-retention element is rigidly connected to the distal portion of the body (when in place in Fig. 17D).

Regarding Claim 11, Gifford teaches the outside-retention element is slidably coupled to the distal portion of the body (when sliding 217 into place in Fig. 17D).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford, III (U.S. Patent No. 5,904,697) in view of Scholz et al. (US 6273912).

Gifford teaches all limitations of preceding independent claim 1, but fails to teach wherein the opening is prepared by a length-wise axial incision from a toe point at the end of the graft tissue conduit to a heel point along the length of the graft tissue conduit, or wherein the opening is prepared by an incision oblique to the longitudinal axis of the graft tissue conduit from a toe point at the end of the graft tissue conduit to a first point along the length of the graft tissue conduit followed by a length-wise axial incision from the first point to a heel point further along the length of the graft tissue conduit. Scholz teaches a graft for end to side anastomosis wherein the opening is formed either by a length-wise axial incision from a toe point at the end of the graft tissue conduit to a heel point along the length of the graft tissue conduit (fig. 4b), or an incision oblique to the

longitudinal axis of the graft tissue conduit (fig. 6b) in order to facilitate the anastomosis, increase compliance matching between the graft and the receiving artery, and optimize hemodynamic flow from the graft into the receiving artery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Gifford by preparing the opening as taught by Scholz in order to facilitate the anastomosis, increase compliance matching between the graft and the receiving artery, and optimize hemodynamic flow from the graft into the receiving artery.

Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford, III (U.S. Patent No. 5,904,697) as applied to claims 1,2 and 44 above.

Gifford teaches the claimed invention as described above but is silent regarding the choice of materials for the embodiment as shown in Fig. 17B. However Gifford states using nitinol (col. 47, ll. 66) in a different embodiment for the elastic properties. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use nitinol as this aids in keeping the fastener secure in the body.

Allowable Subject Matter

Claims 15 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 6/15/10 have been fully considered but are moot in view of a new rejection.

Conclusion

Applicant's amendment dated 11/24/09 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MELISSA RYCKMAN** whose telephone number is (571)272-9969. The examiner can normally be reached on a flexible schedule, email address is melissa.ryckman@uspto.gov.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/Darwin P. Erez/
Primary Examiner, Art Unit 3773